REMARKS/ARGUMENTS

Status of the Claims

Claims 1, 6, 8 and 69 are currently pending. Claim 7 is objected to as being dependent on a rejected base claim. Applicants have traversed the rejection to the base claim, and therefore have chosen not to amend claim 7 at this time. The rejections set forth in the Office Action Mailed July 19, 2006 are traversed by Applicants' arguments set forth below.

Claim rejections under 35 USC §112 first paragraph

The Patent Office rejected claims 1, 6, 8, and 69 under 35 USC §112 first paragraph for failing to meet the written description requirement, based on the assertion that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Patent Office has asserted that Applicants do not have written support in the application as filed for a genus of antibody-conjugated enzymes, in which the antibody recognizes a cell surface antigen on a tumor cell. Applicants traverse this rejection.

As stated in MPEP 2163, "if a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met;" and, "what is conventional or well known to one of ordinary skill in the art need not be disclosed in detail" to satisfy the description requirement. Applicants recite, in the instant claim 1, the limitation that "the antibody recognizes a cell surface antigen on a tumor cell." The Federal Circuit and the Patent Office recognize that the state of the art of making antibodies is highly developed and well understood. *Noelle v. Lederman,* 69 USPQ2d 1508, 1513-1514 (Fed. Cir. 2004), *citing* Synopsis of Application Written Description Guidelines, at 60, available at *http://www.uspto.gov/web/menu/written.pdf.* Thus, since antibody technology, specifically in tumor cells, is well known to one of ordinary skill in the art, additional details do not need to be disclosed.

As noted by the Patent Office, "the specification must provide sufficient distinguishing identifying characteristics of the genus;" and "a description of a genus maybe achieved by means of a recitation of a representative number of species." As stated in the MPEP 2163:

> What constitutes a "representative number" is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed...Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces.

Applicants clearly identify the genus in the instant claim 1 as those antibodies that "recognize a cell surface antigen on a tumor." Applicants further recite a representative number of species as non-limiting examples, including "Herceptin" and "STEAP" on page 13 lines 16-23 and page 14 line 1 and "anti-CD20," "anti-CC49," "Herceptin" on page 44 lines 13-17. The examples all share the common attribute of recognizing cell surface antigens on tumor cells. As discussed in *Noelle v. Lederman*, written description exists for antibodies where the antigen is disclosed, for example, by its physical properties. *Noelle v. Lederman*, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004). Since Applicants provide a number of examples of antibodies that have the physical property of binding to tumor antigens, and numerous other tumor antigens are known in the art and can be readily determined by those of skill in the art using conventional techniques, Applicants submit that the claims satisfy the written description requirement without having to list every antibody in existence that binds to tumor antigens.

Finally, as stated in the MPEP 2163 "the examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled the art would not recognize in the original disclosure a description of the invention defined by the claims." The Patent Office does not present evidence or reasoning to explain why persons skilled in the art would not recognize the recited antibodies as being non-limiting examples of the genus of antibodies that recognize a cell surface antigen on a tumor. Thus, Applicants submit that the specification provides adequate written description for the claimed invention under 35 USC §112, and Applicants respectfully request reconsideration and withdrawal of the rejection.

CONCLUSION

Applicants respectfully contend that all conditions of patentability are met in the pending claims as amended or as originally presented. Allowance of the claims is thereby respectfully solicited.

Applicants believe that no fees are due for this Response. If Applicants are mistaken, please charge any requisite fees to our Deposit Account, No. 13-2490.

If there are any questions or comments regarding this Response, the Patent Office is encouraged to contact the undersigned attorney as indicated below.

Respectfully submitted,

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